Remarks/Arguments:

Claims 1-15, 25-27, and 35-43 were pending in this application. Claims 1, 35-38, and 41 are amended, and claims 44-52 are newly added. Support for newly added claims 44-52 is found in the application at, for example, page 4, lines 26-30. Therefore, claims 1-15, 25-27, and 35-52 are the pending claims in this application.

Claims 1-9, 11, 15, 25-27, 36-38, 42, and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,522,881 to Lentz (Lentz) in view of U.S. Patent No. 5,964,744 to Balbierz et al (Balbierz). Claims 10, 14, and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lentz as modified further in view of U.S. Patent No. 5,769,884 to Solovay (Solovay). Claims 12, 13, 35, 39, and 40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lentz as modified, further in view of U.S. Patent No. 5,824,036 to Lauterjung (Lauterjung). For the reasons discussed below, the applicant submits that the pending claims are patentable over the cited references.

The claimed invention is directed to an implant having improved fixation to a body lumen. Specifically, the invention provides a prosthetic component defined by a graft and a hem formed on the graft wherein the hem defines an interior space. The invention provides a cord disposed in the interior space and adapted for expanding upon absorbing fluid. As recited by claim 1, this serves to aid in fixating the prosthetic component against the body lumen. The application contains independent device claims 1, 35-38, and 41 directed to this invention. Independent method claims 25 and 42 basically recite introducing a device of the invention into a body lumen and then contacting the cord with fluid, while independent method claim 43 recites introducing a device of the invention into a body lumen and then removing an impediment to fluid flow to allow the fluid to contact the cord. Additional dependent claims are discussed below.

In order to establish a *prima facie* case of obviousness, MPEP § 2143 sets forth three requirements. First, there must be some suggestion or motivation to combine the references. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all of the claim limitations. With respect to the rejection of Lentz in view of Balbierz, the applicant contends that, at the very least, that there is no suggestion or motivation to combine these two references.

Turning first to Lentz (and citing its reference numerals), this patent is directed to an implantable prosthesis 10 having integral cuffs 20 and 22. Lentz discloses, and contemplates, inserting only a stent 28 into the cuffs and expanding the stents to anchor the conduit in the body vessel. The cuffs define an open-ended slot 20a and 22a between the cuff and body where the stent is inserted. As described in Lentz, the cuffs are used to house a stent, which is used to affix the prosthesis in place by radial expansion against the inner wall of the body lumen, in a known manner. Col. 3, lines 31-60, and col. 5, lines 18-21. In other words, the only place for the stent (an important part of a prosthetic component) to be disposed in Lentz is in cuffs 20 and 22, and the only component which is envisioned to be disposed there by Lentz is a stent. As recognized in the Office Action, Lentz fails to disclose a cord disposed within the cuffs that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen.

Balbierz is relied upon in the Office Action for its teaching of a cord shaped stent comprising a coated polymer material that expands upon hydration. The Office Action cites Figure 12 in support thereof. As shown in Figure 12 and as described throughout Balbierz, Balbierz is directed to ureteral stent for assisting drainage, for example, from the kidney through the ureter. See Col. 1, lines 26-28. The parent patent of Balbierz, U.S. Patent No. 5,599,291, describes the operation in more detail of a ureteral stent at columns 4 and 5, in connection with Figure 1 of both Balbierz and its parent. Critical to its function, the stent must form a predetermined final cross-ureteral stent outer diameter to provide enhanced fluid passage from kidney 28 to bladder 22. See the '291 patent, col. 5, lines 4-9. The stent defines a lumen 32 extending its entire length with openings at both ends and may also include drainage holes 34. Col. 5, lines 13-17. In sum, to achieve its purposes, it is critical that the device of Balbierz be configured such that it allows flow along its length. Also, the way in which the device of Balbierz is retained in place is by the use of pigtails or enlarged ends that are blocked by virtue of a body becoming narrowed, as shown in Fig. 1A.

The Office Action concludes that it would have been obvious to have incorporated the stent of Balbierz into the hem of the prosthesis of Lentz "in order to produce a prosthesis that is capable of expanding and fixating securely against the walls of a body lumen." First, the applicants contend that this reason is one of the very reasons set forth in applicant's own application. As stated in MPEP § 2143, the suggestion to combine must be found in the prior art, not in applicant's disclosure. Therefore, this reliance on applicant's own disclosure is

improper, and no other valid basis for any motivation to combine the references has been provided. See MPEP § 2143.01.

Perhaps the applicant's own disclosure was relied on because the prior art provides no suggestion or motivation to combine the references. In fact, there are affirmative reasons why one skilled in the art would *not* have combined Lentz and Balbierz. For example, the proposed modification would render Lentz unsatisfactory for its intended purpose. The shape of the stent of Balbierz, for example as shown in Figure 12, would not fit adequately in the hems of Lentz. Even if one skilled in the art would have thought to use the stent of Balbierz at a single axial point in the body lumen, instead of along the length of a body lumen as shown and described in Balbierz, the necessary pigtails or enlarged ends of Balbierz would create a significant problem if applied to Lentz. The pigtails would protrude into the flow path and/or the wall of the body lumen in a transverse direction, creating great strain on both the prosthesis and the body lumen.

More generally, the applicant contends that one skilled in the art, when viewing Balbierz, would not have considered the stent disclosed therein for use at a single axial point like the stent of Lentz. As mentioned above, an important part of the stent of Balbierz is that it allows for and in fact enhances fluid flow along its length, such as from a kidney to a bladder. Thus, to place it at only one axial point is counterintuitive to its envisioned use. Moreover, another reason which would actually dissuade one skilled in the art from making the proposed combination is that the hem of Lentz in many applications is shielded from fluid (i.e., blood) flow by the graft material. On the other hand, the emphasis of the stent in Balbierz is just the opposite, making it even more clear that one skilled in the art would not have been motivated to make the proposed combination.

The rejections of all of the remaining claims rely on the combination of Lentz and Balbierz. The applicant contends that these rejections are improper for the same reasons set forth above.

Moreover, newly added dependent claims 44-52 recite that the cord consists of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid. Balbierz fails to disclose or suggest such a material.

As described at col. 16, line 35 through col. 17, line 8 in connection with Figure 12, the stent of Balbierz is made of a shape memory material including both a hydrophilic polymer and a non-hydrophilic polymer, which is annealed to provide a shape memory (as shown in Figure 12a) and then coated with a hydrogel to harden and hold the stent in a second configuration, as shown in Figure 12b. Upon hydration, the hydrogel dissolves away and the hydrophilic polymer loses its mechanical strength, thus allowing the ends of the stent to return to their original shape. For completeness, the applicant notes that Balbierz does disclose that the hydrophilic polymer may soften and expand upon hydration. Nonetheless, Balbierz fails to disclose or suggest the stent being made of a single material (to the exclusion of the first or non-hydrophilic polymer) which absorbs fluid and expands as a result of the absorption of fluid; instead, Balbierz relies on, at least in part, the shape memory stored in the first or non-hydrophilic polymer to achieve its final configuration. Accordingly, Balbierz cannot be said to disclose a stent which "consists of" an absorbent material as claimed by claims 44-52.

For the reasons discussed above, the applicant respectfully submits that claims 1-15, 25-27, and 35-52 are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,

Christopher R. Lewis, Reg. No., 36,201
Attorney for Applicant

CRL\JA\bgd

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P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

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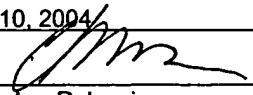

Christopher R. Lewis

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